

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

Carpmaels & Ransford
Attn. Brunner, John Michael O
43-45 Bloomsbury Square
London WC1A 2RA
GRANDE BRETAGNE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year) 22/01/2010	
Applicant's or agent's file reference P050907WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/GB2009/001446	International filing date (day/month/year) 10/06/2009
Applicant CILAG GMBH INTERNATIONAL	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90**bis**.1 and 90**bis**.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Myriam Weber

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

From the INTERNATIONAL BUREAU

JMB

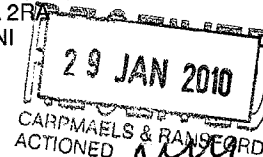
PCT

FIRST NOTICE INFORMING THE APPLICANT OF
THE COMMUNICATION OF THE INTERNATIONAL
APPLICATION (TO DESIGNATED OFFICES WHICH
DO NOT APPLY THE 30 MONTH TIME LIMIT
UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

BRUNNER, John, Michael, Owen
Carpmaels & Ransford
43-45 Bloomsbury Square
London WC1A 2RA
ROYAUME-UNI



Date of mailing (day/month/year) 21 January 2010 (21.01.2010)		
Applicant's or agent's file reference P050907WO		IMPORTANT NOTICE
International application No. PCT/GB2009/001446	International filing date (day/month/year) 10 June 2009 (10.06.2009)	Priority date (day/month/year) 19 June 2008 (19.06.2008)
Applicant CILAG GMBH INTERNATIONAL et al		

1. **ATTENTION:** For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93bis.1. The International Bureau has effected that communication on the date indicated below:
23 December 2009 (23.12.2009)

None

In accordance with Rule 47.1(c-bis)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93bis.1 :

LU, TZ, UG

In accordance with Rule 47.1(c-bis)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. TIME LIMITS for entry into the national phase

For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph**, be **20 MONTHS** from the priority date.

In practice, **time limits other than the 20-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For **regular updates on the applicable time limits** (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

It is the applicant's **sole responsibility** to monitor all these time limits.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Dorothee Mülhausen
Facsimile No. +41 22 338 82 70	e-mail: pt01.pct@wipo.int

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P050907WO	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/GB2009/001446	International filing date (day/month/year) 10/06/2009	(Earliest) Priority Date (day/month/year) 19/06/2008
Applicant CILAG GMBH INTERNATIONAL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 3a
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
 b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB2009/001446

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A fluid transfer assembly (10) comprises means (12) for connection to a syringe and receiving means (11) for receiving a vial (14) having a closure element (14a). The receiving means (11) is adapted to engage and open the closure element (14a) and permit fluid in the vial (14) to be transferred to the syringe from the vial, for example by gravity acting on the fluid in the vial.

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/001446

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61J1/20 A61M5/20 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61J A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/079834 A1 (TENNICAN PATRICK O [US] ET AL) 13 April 2006 (2006-04-13)	1-8
Y	paragraphs [0049], [0115]; figures	9-10, 16
A	1, 2, 16B	18
X	WO 00/07539 A (BAXTER INT [US]) 17 February 2000 (2000-02-17)	1
	page 10, paragraph 10 - paragraph 14 figures 2B, 3, 4B, 6B	
Y	FR 2 717 086 A (DEBIOTECH [CH]) 15 September 1995 (1995-09-15)	9-10, 16
	page 18, line 12 - line 22 page 20, line 6 - line 36 figures 10a-10d	
	----- -/-- -----	

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

12 January 2010

Date of mailing of the international search report

22/01/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Sedy, Radim

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/001446

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/178631 A1 (GILLESPIE RICHARD D [US] ET AL) 10 August 2006 (2006-08-10) paragraphs [0050], [0061], [0062]; figures 2,3,6-8	9,11-12
A	US 5 137 516 A (RAND PAUL K [US] ET AL) 11 August 1992 (1992-08-11) column 6, line 55 - column 7, line 3; figures 1,2	9,13-15, 17-18
A	US 2006/069350 A1 (BUENGER DAVID R [US] ET AL) 30 March 2006 (2006-03-30) paragraphs [0024], [0026], [0029], [0032], [0033]; figures 6-9	9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2009/001446

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8

Claims 1-7:

fluid transfer assembly having:

- a) means suitable for connection to a syringe;
- b) means suitable for receiving a vial having a closure element

(purpose: simple fluid transfer means)

Claim 8:

fluid transfer assembly having the fetures a) and b);

c) a syringe

(purpose: means improving the filling of a syringe)

2. claims: 9-18

Claims 9-15:

injection kit having:

features a), b) and c);

d) delivery device having:

e) delivery sub-assembly and

f) drive sub-assembly

(purpose: improving of delivering fluid from a syringe)

Claims 16-18:

method of assembling an injection device including the setps of:

g) inserting fluid into a syringe;

h) inserting the syringe into a delivery sub-assembly;

i) attaching a sub-assembly having a drive to the delivery sub-assembly

(purpose: making a syringe ready for injection)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001446

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006079834	A1	13-04-2006	
		AU 2005296001 A1	27-04-2006
		BR PI0515999 A	19-08-2008
		CA 2583601 A1	27-04-2006
		EP 1799285 A2	27-06-2007
		JP 2008515594 T	15-05-2008
		SG 156642 A1	26-11-2009
		US 2007249996 A1	25-10-2007
		US 2007260176 A1	08-11-2007
		US 2007265574 A1	15-11-2007
		US 2007265578 A1	15-11-2007
		US 2007255203 A1	01-11-2007
		US 2007255226 A1	01-11-2007
		US 2007276322 A1	29-11-2007
		WO 2006044236 A2	27-04-2006
WO 0007539	A	17-02-2000	
		US 6358236 B1	19-03-2002
FR 2717086	A	15-09-1995	
		NONE	
US 2006178631	A1	10-08-2006	
		NONE	
US 5137516	A	11-08-1992	
		AR 246185 A1	29-07-1994
		AT 400925 B	25-04-1996
		AU 639955 B2	12-08-1993
		AU 6691290 A	06-06-1991
		BE 1003835 A5	23-06-1992
		BR 9006006 A	24-09-1991
		CA 2030742 A1	29-05-1991
		CH 687234 A5	31-10-1996
		CZ 9702029 A3	11-08-1999
		DE 4037418 A1	29-05-1991
		DK 281990 A	29-05-1991
		ES 2038088 A6	01-07-1993
		FI 905832 A	29-05-1991
		FR 2654938 A1	31-05-1991
		GB 2239180 A	26-06-1991
		GR 90100824 A	17-04-1992
		HK 19295 A	17-02-1995
		HU 61207 A2	28-12-1992
		IE 904240 A1	05-06-1991
		IL 96487 A	26-05-1995
		IN 179332 A1	27-09-1997
		IT 1243541 B	16-06-1994
		JP 3222962 A	01-10-1991
		JP 3399524 B2	21-04-2003
		LU 87851 A1	25-08-1992
US 5137516	A		
		NL 9002598 A	17-06-1991
		NO 905125 A	29-05-1991
		NZ 236219 A	23-12-1992
		PL 287996 A1	12-08-1991
		PT 96005 A	31-08-1992
		SE 469262 B	14-06-1993
		SE 9003776 A	29-05-1991
		RU 2108116 C1	10-04-1998
		ZA 9009514 A	27-11-1991
US 2006069350	A1	30-03-2006	
		NONE	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001446

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
<p>1. <i>Patent document cited in search report</i></p> <p>2. <i>Publication date</i></p> <p>3. <i>Patent family member(s)</i></p> <p>4. <i>Publication date</i></p>			

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2009/001446

International filing date (day/month/year)
10.06.2009

Priority date (day/month/year)
19.06.2008

International Patent Classification (IPC) or both national classification and IPC
INV. A61J1/20 A61M5/20 A61M5/50

Applicant
CILAG GMBH INTERNATIONAL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Sedy, Radim

Telephone No. +31 70 340-2978



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/001446

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/001446

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☒ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. 1-18

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>9-18</u>
	No: Claims	<u>1-8</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-18</u>
Industrial applicability (IA)	Yes: Claims	<u>1-18</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/001446

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

Reference is made to the following documents:

- D1 US 2006/079834 A1 (TENNICAN PATRICK O [US] ET AL) 13 April 2006 (2006-04-13)
- D2 WO 00/07539 A (BAXTER INT [US]) 17 February 2000 (2000-02-17)
- D3 FR 2 717 086 A (DEBIOTECH [CH]) 15 September 1995 (1995-09-15)
- D4 US 2006/178631 A1 (GILLESPIE RICHARD D [US] ET AL) 10 August 2006 (2006-08-10)
- D5 US 5 137 516 A (RAND PAUL K [GB] ET AL) 11 August 1992 (1992-08-11)
- D6 US 2006/069350 A1 (BUENGER DAVID R [US] ET AL) 30 March 2006 (2006-03-30)

1 INDEPENDENT CLAIM 1

- 1.1 The lack of clarity notwithstanding (see Item VIII below), the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met. The document D1 discloses (see e.g. paragraphs [0049] and [0115], figures 1,2,16B) the references in parenthesis applying to this document:

A fluid transfer assembly (200) having:

means *suitable* for connection to a syringe;

receiving means (600) *suitable* for receiving a vial having a closure element, wherein the receiving means is adapted (= *suitable*) to engage and open the closure element and permit fluid in the vial to be transferred to the syringe from the vial.

Consequently, this document discloses all the features of claim 1 so that its subject-matter cannot be considered novel.

Moreover, in addition to D1, also D2 (see passages cited in the search report) presents a prior art document which clearly discloses a fluid transfer assembly such as defined by claim 1.

2 DEPENDENT CLAIMS 2-8

- 2.1 Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, see for example:

D1, paragraphs [0049] and [0115], figures 1, 2, 16B, for **claims 2-8**.

Remark:

Claim 8 discloses all the features of claim 1. Therefore, it is to be considered as a claim being dependent on claim 1.

3 INDEPENDENT CLAIM 9

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 9 does not involve an inventive step in the sense of Article 33(3) PCT.

- 3.2 The document D3 is regarded as being the closest prior art to the subject-matter of claim 9, and discloses (see e.g. paragraphs [0049] and [0115], figures 1, 2, 16B):

an injection kit comprising:

the fluid transfer system of claim 8.

- 3.3 The subject-matter of independent claim 9 differs from the disclosure of D1 in that the kit further comprises:

a delivery device including a delivery sub-assembly and a drive sub-assembly, which are both adapted to be attached to the syringe, and operate together to deliver the fluid from the syringe.

Consequently, the subject-matter of claim 9 is novel with respect to Article 33 (2) PCT.

- 3.4 The problem to be solved by the present invention may therefor be regarded as providing an injection kit in which the way for a patient to transfer a subcutaneous drug from a vial into an auto-injector is made easier.

- 3.5 The solution proposed in claim 9 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The delivery device including a delivery sub-assembly (see *pièce de guidage* 14'') and a drive sub-assembly (202) as described in the document D3 are providing the same advantages as in the present application (see e.g. page 20, lines 6-36). Specifically, the delivery sub-assembly (14''), which has been attached to the syringe for filling purposes, is left in place while serving to further attaching the syringe to the drive sub-assembly (202). The skilled

person, who is supposed to be in possession of D3, would therefore regard it as a normal option to include these features in the fluid transfer assembly described in document D1 in order to solve the problem posed.

Consequently, the subject-matter of claim 9 does not involve an inventive step in the sense of Article 33(3) PCT.

4 INDEPENDENT CLAIM 16

- 4.1 Similar argumentation with respect to inventive step (see point 3 above) can be applied mutatis mutandis regarding the subject-matter of claim 16.

5 DEPENDENT CLAIMS 10-15, 17 AND 18

- 5.1 Dependent claims 10-15, 17 and 18 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of inventive step, see documents D3-D6 and the corresponding passages cited in the search report.

Re Item VII.

- 1 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII.

- 1 Claim 1: The wording "means for connection to a syringe"; and " *receiving* means for receiving a vial" used in claim 1 is unclear, contrary to the requirements of Article 6 PCT, because these "means" are merely defined by their suitability to other features which are not part of the claim. Consequently, it remains unclear what is meant by "means" as such since they do not specify any concrete technical features of the claimed fluid transfer assembly.
- 2 Claim 4 is not clear, contrary to the requirements of Article 6 PCT, insofar as the receiving means is defined by reference to " *the vial*" which is not part of the claim. According to claim 1 on which claim 4 is dependent, the receiving means is merely suitable for "... receiving a vial having a closure element".

- 3 Probably, claim 10 should have been made dependent of claim 9 in place of "8".
- 3.1 Moreover, also claims 17 and 18 appear to depend on incorrect claim numbers.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
---------------------	---

Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
-----------------------------------	---

Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
---	---

Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
--------------------------	--

End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
--------------------------------	---

Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003
---	--